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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,425	02/19/2002	Harold G. Brown	2059-0103P	1812

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EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	**PAPER NUMBER**
1651	

NOTIFICATION DATE	DELIVERY MODE
10/01/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	09/890,425	BROWN ET AL.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *24-27, 30, 32-35, 52, 97-111,116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 7-9,11,12,14,19,22-27,30,32-37,41,42,46-48,51-54,59,66,69,70,72-94 and 97-128.

DETAILED ACTION

This Office Action is in response to the Applicant's reply received 7/25/07. Claims 7, 8, 9, 11, 12, 14, 19, 22, 23, 24-27, 30, 32-35, 36, 37, 41, 42, 46-48, 51, 52, 53, 54, 59, 66, 69, 70, 72-94, 97-111, 112-115, 116, 117-127, 128 are pending. Claims 24-27, 30, 32-35, 52, 97-111,116 are withdrawn. Claim 128 is new. The Examiner acknowledges the interview with Marc Wiener and Karen Brown on 7/19/07.

Response to Claim Objections

The objection to claim 117 is withdrawn in view of Applicant's amendment.

Response to Applicant's Arguments— 35 U.S.C § 112

Also the 35 U.S.C § 112 rejection of claims 49, 122 and 123 are withdrawn in light of the Applicant's amendment.

Response to Applicant's Arguments— 35 U.S.C § 102

In the response submitted by the Applicant, the 35 U.S.C § 102 (b) rejection of claims 7, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-76, 91-94, 112, 113, 115, and 117-127 over Turley et al. (WO 97/25051) were considered but not found persuasive.

The Applicant argues once more how the molecular weight measurement for the glycosaminoglycan hyaluronic acid (hyaluronan) was measured by Turley et al. using the less accurate Dextran Standard. The Applicant points out that they used an alternative standard and submits a 37 C.F.R. 1.132 declaration successfully proving this point. But was not persuasive to overturn the rejection for the following reasons.

However the Examiner is bound to examine the claims as written with the broadest reasonable interpretation. As stated in the previous Office Action:

> "The arguments concerning the difference between the protein standard and dextran standard are not commensurate within the scope of the claims. The claims do not specifically mention how the molecular weight of the carbohydrates are determined but simply states "molecular weight ranges" and gives no indication on which method is used to obtain those ranges. Therefore the reference of Turley et al. still reads on the applicant's invention since the claims do no clearly state how the molecular weight of the carbohydrates are obtained." (Office Action, mailed 3/15/07, page 5-6).

Furthermore at the claims are now written they simply use the unit of Daltons. The unit of Daltons is a fixed unit of mass ($1/12^{th}$ of the weight of a carbon atom) and is inherent in the molecule. However the Examiner is certain that the Applicant is not arguing that the two mass standards change the weight of a single molecule but until the components of the 37 C.F.R. 1.132 declaration are incorporated into the claims and make clear the apparent molecular weight based on a particular standard, the art of Turley et al. remains.

The Applicant defines in great detail the relationship between the protein standard and the intrinsic viscosity of the glycosaminoglycan however this limitation and comparison is not in the claims and as such is not commensurate with the scope of the claims.

The Applicant mentions that the European Examiner was convinced by the 37 C.F.R. 1.132 declaration. However, while this Examiner has substantial respect for the skill his European counterparts, this Examiner is not bound to the examination of a foreign country. As such this Examiner maintains the rejection and rational for the 35 U.S.C § 102(b) rejection made in the previous Office Action which is now repeated.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-76, 91-94, 112, 113, 115, and 117-127 remain rejected under 35 U.S.C. 102(b) as being anticipated by Turley et al. (WO 97/25051, 1997)

Turley et al. discloses a product comprising a molecular weight hyaluronic acid (a glycosaminoglycan) fraction having a molecular weight in the range of about 30,000 to 2 million Daltons (page 5, lines 4-28) and specifically states 178,000 Daltons (page 7, line 16) in a pharmaceutical composition of a 1% by weight solution in sterile water that can be administered orally as a drink (page 5 lines 5-10). Turley et al. teach that the hyaluronic acid used in their composition can use a pharmaceutical grade of hyaluronic acid that contains not more than (**NMT**) 0.10% by weight protein or a topical grade of hyaluronic acid that contains NMT 0.40% by weight protein (page 7 and 8, see Protein Content). Several claims recite the limitation that the complex carbohydrate "will cause an inflammatory response when injected into owl monkey eyes but will not cause an adverse reaction when applied to the skin of mammals or when delivered orally or mucosally to mammals" or the composition is "pharmacologically effective". These are functional limitations that define the composition by what it does rather than what it is

(M.P.E.P. § 2173.05(g)) and as such since the composition meets the physical limitations of the composition it must therefore inherently meet the functional limitation.

Also claims 46-49 list several intended uses for the composition such as pain-relief and tumor prevention or treatment. Composition claims are evaluated based on their structural limitations. Intended uses such as those mentioned above do not provide any structural limitations to the composition and are therefore ignored (M.P.E.P. § 2111.02 II).

Therefore the reference anticipates claims 2, 3, 6, 7, 19, 22, 23, 36, 37, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 72-76, 91-94, 112, 113, 115, and 117-127.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 over Turley et al. with support from Sharma et al. and Weitzberg et al. were considered but not found persuasive. Similarly the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 7,8, 11,12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 over Turley et al. in view of Taylor-McCord were considered but not found persuasive. Also the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 7, 9, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 over Turley et al. in view of Gaeta et al. were considered but not found persuasive.

The Applicant repeats the argument as above that because the standards used to measure the molecular weight of the hyaluronic acid (a glycosaminoglycan) used by Turley et al. is different from that used by the Applicant that the rejection now fails to meet all the limitations. However as mentioned above the argument is not commensurate with the scope of the claims cannot be considered until the claims reflect

some limitation to the standard of measurements used to mass the glycosaminoglycans. Therefore the rejection stands and is repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Turley et al. (WO 97/25051, 1997) as applied to above with support from Sharma et al. (U.S. Patent # 4,933,183, 1990) and Weitzberg et al. (U.S. Patent # 5,079,260).

Claims 11-14 further limit the composition of claim 19 by requiring carbohydrates with a mixture molecular weight ranges. While this is not specifically taught by Turley et al. he does mention that their composition does contain dosage forms of hyaluraonan which the human body can easily use (page 5, lines 5-10). They define these two ranges of hyaluronan used by the body from 30,000 to greater than 2 million Daltons and the range 30,000 to greater than 70,000 daltons (page 4, lines 22-31). While Turley et al. teach using a composition with one molecular weight or the other it would be obvious for one of ordinary skill in the art to add both molecular weights (page 5, lines 4-30) according to M.P.E.P. § 2144.06 which states

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form

> a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more sizes of hyaluronic acid to the composition of Turley et al. since he teach that both molecular weights can be used by the body to treat the same diseases such as heart attack and stroke.

Claim 13 limits the chemical composition of the complex carbohydrates as differing by molecular weight and chemical structure. However, these carbohydrates are polymers and their chemicals structure is dependant on molecular weight. Therefore since the molecular weights of Hyaluronic acid are different the chemical structure of the polymers must be different.

Claims 77-90 limit the final formulation of the composition. They limit the composition to a candy, mouthwash, tablet etc. While Turley et al. does teach an ingestible or topical composition they do not specifically teach these formulations. However it would be obvious to one of ordinary skill in the art to make ingestible formulations in these forms since these forms are obvious equivalents that are well known in the art (see M.P.E.P. § 2144.06) to make a medicament as supported by Sharma et al. (col 8, lines 31-50) and Weitzberg et al. (col 6, lines 18-30).

Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 7, 11, 12, 14, 19,

22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 are not allowable.

Claims 7, 8, 11,12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Turley et al. as applied to the claims above, and further in view of Taylor-McCord (U.S. Patent # 5,604,200, 1997).

The description of claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 and how they are rendered obvious are detailed in the rejection by Turley et al. above.

Claims 8 and 60 limit their respective compositions by requiring the polysaccharide mannan. Turley et al. teach a topical composition that contains hyaluronic acid to be applied topically to the skin (page 14, lines 19-21) such as an wound site with scar tissue (page 14, lines 10-15). Taylor-McCord et al. teach a compositions for topical treatment of the skin that has been injured (col 8, lines 14-21) that also contains hyaluronic acid (col 11, Example II and col 12, Claim 1) that can have a concentration of hyaluronic acid of 0.05% to 2.00% by weight (col 12, claim 4) as well as Aloe Vera extract which one of ordinary skill in the art would recognize would contain mannas. It would have been obvious to someone skilled in the art to combine the inventions of Turley et al. and Taylor-McCord since both teach a composition that contains hyaluronic acid for skin treatment and M.P.E.P. § 2144.06 states that,

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more Aloe Vera extract which comprises mannan to the a composition already comprising hyaluronic acid of Turley et al for topical treatment. Therefore the references listed above renders obvious claims 7, 8, 11,12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127.

Claims 7, 9, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Turley et al. as applied to claims 7, 8, 11,12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 above, and further in view of Gaeta et al. (U.S. Patent # 5,559,103, 1996).

The description of claims 7, 8, 11,12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 and how they are rendered obvious are detailed in the rejection by Turley et al. above.

Claim 9 further limits the composition to comprise a sialylated sugar. While Turley et al. teach a composition comprising hyaluronic acid for the use of strokes or heart attack victims (see abstract). They do not teach the use of a sialylated sugar in

their composition. This is taught by Gaeta et al. who teach a sialylated sugar for a pharmaceutical composition to treat patients of heart surgery (col 30 lines 59-62) and those who recently experienced a stroke or heart attack (col 31, lines 1-5). Since sialylated sugar compositions and hyaluronic acid compositions treat the same diseases it would have been obvious to someone skilled in the art to combine the compositions to treat heart and stroke victims. According to M.P.E.P. § 2144.06 which states

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add sialylated sugars to the composition of Turley et al. Therefore the references listed above renders obvious claims 7, 9, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127.

Allowable Subject Matter

New Claim 128 is free of the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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